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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,152	02/08/2001	Leigh T Canham	124-821	3931
23117	7590	12/18/2003		
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			EXAMINER DEO, DUY VU NGUYEN	
			ART UNIT 1765	PAPER NUMBER

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,152

Applicant(s)

CANHAM ET AL.

Examiner

DuyVu n Deo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-17 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-17 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1,661
1/22/01
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1-35 and canceling of non-elective claim 36 in Paper No. 8 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-8, 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginavan et al. (US 5,457,041).

In regard to claims 1-15, Ginavan discloses a method for providing a silicon micro needle (col. 8, lines 52-62), the micro needle having a base adjoining a substrate (see fig. 1, where "16" is the substrate and "12" is the micro needle, which adjoins the substrate through its "base" or lower portion; see also col. 7, lines 3-7); a tip remote from the base (col. 7, line 14 and also fig. 1, where it is shown that needle tips "28" are on the opposite side of the base, or "remote from said base"); and a region between the tip and the base (see fig. 1, the region between tip "28" and the base adjoining substrate "16"; see also col. 7, lines 55-67), which reads on applicant's "duc", and "wherein the duct passes substantially between the tip and the base"; and wherein the method comprises providing said duct (col. 7, lines 55-67 and fig. 7) and selectively removing the substrate from around the duct to provide the micro needles "coincident" with the duct (col. 8, lines 59-67 and col. 9, lines 1-29). Furthermore, Ginavan discloses the use of a mask (col. 9,

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lines 14-29), the use of plasma etching, anisotropic etching, etching with a resist mask and several other etching procedures for the removal of material (col. 9, lines 55-65).

In regard to claim 16, it is noted that figs 1-5 show that the walls of micro needle "12" can be flat, pointed, jagged, concave, or hollow (see also col. 7, lines 53-65) and it is believed that some of these different shapes read on applicant's limitation that the micro needles are "inclined to a plane that is perpendicular to the substrate."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 17, 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginavan as applied to claims 1, 3-8, 10-16 above, and further in view of Busta et al. (US 5,137,817).

In regard to claims 17-35, these claims differ from claims 1, 3-8, 10-16 above by adding the limitation that the base of the micro needle adjoins a first material, while the duct is lined with a second material, thereby forming a two-material micro needle.

Ginavan does not disclose a two-material micro needle as the claimed invention does. Busta discloses the formation of what he calls "electrodes" which read on applicant's "micro needles", and discloses that they adjoin a first material, are lined by a second material and are thereby formed of the two materials (col. 10, lines 51-68 and col. 1, lines 1-62). Busta teaches that the use of two materials for the micro needle allow for lower voltage requirements, easier access to their targets and rapid treatment times (col. 4, lines 20-44). Furthermore, Busta

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discloses that the duct of the electrode or micro needle is linked to a reservoir (col. 11, line 5-10, and 25-31).

It is examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ginavan by utilizing two materials for the formation of the micro needles, as per Busta, because this is a well known procedure in the art and, furthermore, because this modification could result in lower voltage requirements, easier access to their targets and rapid treatment times, which is extremely desirable.

Response to Arguments

6. Applicant's arguments filed 5/19/03 have been fully considered but they are not persuasive.

In response to applicant's arguments, the recitation a duct passing from said base to said tip has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Referring to applicant's argument that there is no reason or motivation for one skill in the art to combine teaching of Busta's electrodes with the micro needle in Ginavan. As show by Busta in fig. 4C and col. 10, lines 39-50, these points electrodes are micro needles for carrying cell transformant and transfer to target cells. The micro needle taught by Ginavan also to carry biological substances for transferring into target cells (col. 4, line 11-15). Therefore, at the time

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of the invention, one skill in the art would find it obvious to combine teaching of Busta with Ginava because this is a well known procedure in the art and, furthermore, this modification could result in lower voltage requirements, easier access to their targets and rapid treatment times according to Busta col. 4, lines 20-44, which is extremely desirable.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DuyVu n Deo whose telephone number is 571-272-1462.

DVD
12/12/03

Nadine G. Norton
NADINE G. NORTON
PRIMARY EXAMINER
SUPERVISOR